PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/11, A61F 2/06 — A1

(11) International Publication Number: **WO 00/49951**

(43) International Publication Date: 31 August 2000 (31.08.00)

(21) International Application Number: PCT/IT00/00058

(22) International Filing Date: 23 February 2000 (23.02.00)

(30) Priority Data:
RM99A000127 24 February 1999 (24.02.99) IT

(71)(72) Applicants and Inventors: GARGIULO, Mariano [IT/IT]; Via Cristoforo Colombo, 14, I–80061 Massalubrense (IT). QUARTO, Gennaro [IT/IT]; Via Appia, Parco Giulia, I–81023 Centurano (IT).

(74) Agents: BANCHETTI, Marina et al.; Ing. Barzano' & Zanardo Roma S.p.A., Via Piemonte, 26, I–00187 Roma (IT).

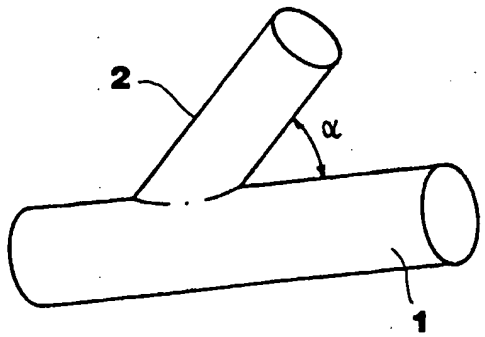
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: AN ADAPTER FOR VASCULAR ANASTOMOSES

(57) Abstract

An adapter for vascular anastomoses having perimetral edges, characterized in that it comprises at least one main conduit (1, 1') and at least one branch conduit (2), the prosthesis being realized with bio–compatible material.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

AN ADAPTER FOR VASCULAR ANASTOMOSES

This invention relates to an adapter for vascular anastomoses.

More particularly, this invention relates to an adapter of the above mentioned kind that enables in reliable and economically feasible way to simplify and speed-up the installation of vascular anastomoses in order to improve the results that can be obtained.

It is known that one of the most frequent surgical intervents is the installation off a vascular by-pass, which represents the surgical treatment of occlusive diseases of arterial, venous or lymphatic vessels as well as in aneurysms. In particular, a vascular by-pass in which an artifact conjunction between interested hollow structures is realized by means of a prosthetic structure, becomes necessary in all those subjects in which particular disease conditions or traumatic events resulted into stenosis, occlusion or dilatation of the vessels.

The installation of a vascular by-pass provides for installation of a connection bridge made of bio-compatible or biologic (autologous, homologous or eterologous) synthetic material designed to span the deteriorated segment, in order to restore the normal arterial, venous or lymphatic circulation. When extended vascular pathologies are involved, the vessels interested in this intervent can be two or more than two. The intervent includes the insertion of the vascular prosthesis, suitably dimensioned by the surgeon during the intervent itself, upon suitably shaping its ends according to the needs (for instance with a so-called clarinet beak cut), onto the one or more interested vessels upstream and downstream the deteriorated segment.

The difficulties connected with installing a vascular anastomosis (namely the suturation between interested hollow structures) are quite apparent to those skilled in the art. The problems arising in suitably shaping the connection orifices as well as in inserting the vascular prosthesis into the usually weakened walls of the interested vessels can be mentioned by way of exemplification.

This entails intervents of extremely long durations, variable as a function of the difficulties to be solved, that can make it necessary to realize a number of anastomoses during the same intervent. In this respect, it has been shown that, for instance, a prolonged duration of an intervent amounts to a significant infection risk for the vascular prosthesis, as well as to an increased surgical risk in general terms.

Furthermore, the outcome of the intervents depends in noticeable amount on the specific skillness of the surgeon, with the risk of technical inaccuracies that can make a reintervention necessary.

Again, the difficulties in vascular anostomoses make the installation of a by-pass on vessels of small diameter very hard.

Additionally, the recently performed by-pass intervents in the frame of video-aided surgery contemplate the realization of the anastomoses as the moment of maximum technical difficulty.

In this contest, it is the object of this invention, therefore, to provide in reliable and economically feasible manner all suitable means to solve all above mentioned problems and to enable to simplify and to speed-up the realization of vascular anastomoses, thereby improving and making the results of such operations as much as possible independent of the skillness of the surgeon.

It is specific subject matter of this invention an adapter for vascular anastomoses, having perimetral edges, characterized in that it comprises at least one main conduit and at least one branch conduit, the prosthesis being realized in bio-compatible material, preferably Dacron® and/or GoreTex® and/or PTFE and/or polyurethane and/or Nitinol® and/or ePTFE.

According to this invention, the adapter can comprise a single main conduit and the axes of the main conduit and of said at least one branch conduit can include an acute angle in the range of 15° to 75°, preferably in the range of 25° to 45°.

Still according to this invention, the adapter can comprise two main conduits and a single branch conduit.

Further according to this invention, at least one branch conduit can comprise a second order branch conduit, the axes of said at least one branch conduit and of said at least one second order branch conduit including an acute angle in the range of 15° to 75°, preferably in the range of 25° to 45°.

Preferably according to this invention, at least one of the conduits of the adapter is of cylindrical or frusto-conical shape and/or it has a circular cross-section.

Again according to this invention, at least one of the conduits of the adapter can have one or more apertures in its external wall.

Again according to this invention, at least one of the conduits of the adapter can be provided with suitably shaped weakness lines in its external wall adapted to be cut so as to remove at least a portion of said external wall.

Preferably according to this invention, said perimetral edges are tapered and/or realized with partially bio-degradable and/or shape recovering materials.

Further according to this invention, at least one of the conduits of the adapter can be provided with an internal metal bio-compatible core, preferably of steel and/or titanium and/or a shape recovering material.

This invention will be hereinafter described, by way of illustration, not by way of limitation, according to its preferred embodiments, by particularly referring to the Figures of the enclosed drawings, in which:

Figure 1 is a perspective view of a first embodiment of the adapter for vascular anastomoses according to this invention,

Figure 2 is a perspective view of a second embodiment of the adapter for vascular anastomoses according to this invention,

Figure 3 is a perspective view of a third embodiment of the adapter for vascular anastomoses according to this invention,

Figure 4 is a perspective view of a fourth embodiment of the adapter for vascular anastomoses according to this invention.

Similar reference numerals will be utilized in the following description to designate similar items in the Figures.

By referring now to Figure 1, it can be observed that the adapter for vascular anastomoses according to this invention comprises a main conduit 1 communicating with a branch conduit 2. Said main conduit 1 and said branch conduit 2 have a cylindrical or frusto-conical shape, with circular cross-section. The axes of said main conduit 1 and said branch conduit 2 include an acute angle α in the range of 15° to 75°, preferably in the range of 25° to 45°.

The adapter according to this invention is realized with bio-compatible materials, such as, for instance, Dacron®, Gore-Tex®, PTFE, polyurethane, Nitinol®, ePTFE.

As it appears in Figure 1, the main conduit 1 communicates with a single branch conduit 2 and the length of said main conduit 1 is greater than the length of said branch conduit 2. It should be understood,

however, that those skilled in the art will be certainly able to modify the adapter according to this invention by providing more than one branch conduit 2 communicating with the main conduit 1 and/or said main conduit 1 can also be no longer than said branch conduit 2, without so departing from the scope of this invention.

Aiming at better illustrating this invention, the employment modes of the preferred embodiment of the adapter for vascular anastomoses will be hereinbelow described, in the assumption that similar modes also apply for the remaining embodiments.

During the realization of a vascular anastomosis, for performing the connection between the vascular prosthesis and the interested vessel, it sufficient to cut open the wall of the interested vessel, to insert the main conduit 1 of the adapter thereinto and to fix it in place. The vascular prosthesis is subsequently externally fixed to the free end of the branch conduit 2 of the adapter.

Aiming at minimizing the step effect that is generated in the lumen of the vessel as well as at enabling an optimum match to be realized between prosthesis and vessel, the free ends of said main conduit 1 can be tapered and/or realized with special partially bio-degradable and/or foamable materials of shape recovering type, that is to say such materials that at temperatures lower than the physiologic temperatures can be stored in slightly deformed condition and at physiologic temperatures they recover their original shape. As far as the adapter according to this invention in concerned, the free ends of said main conduit 1, realized with the above mentioned shape recovering materials, could also be maintained in a compressed diameter configuration and, as soon as they are warmed-up by contact with the blood or lymph stream, they dilatate so as to adhere to the internal wall of the vessel into which the adapter is inserted.

It will be apparent to those skilled in the art that, by utilizing the adapter according to this invention, the installation of a vascular anastomosis is noticeably simplified, which results into dramatically decreasing the necessary times for execution of the related operations as well as into significantly improving the outcome that can be achieved, which, in turn, is substantially independent of the operator's skillness.

By referring to figure 2, it can be observed that a second embodiment of the adapter according to this invention further comprises a

second order branch conduit 3 departing from said branch conduit 2. Said second order branch conduit 3 also has a cylindrical or frusto-conical shape with a circular cross-section. The axes of said branch conduit 2 and of said second order branch conduit 3 include an acute angle β in the range of 15° to 75°, preferably in the range of 25° to 45°.

In Figure 2, the axes of the main conduit 1, of the branch conduit 2 and of the second order branch conduit 3 are co-planar. It should be understood, however, that those skilled in the art can easily modify the adapter according to this invention by realizing said three conduits 1, 2 and 3 with non co-planar axes, without so departing from the scope of this invention.

The embodiment shown in Figure 2 enables to utilize the adapter according to this invention in realizing a vascular anastomosis in which it is necessary to realize multiple connections corresponding to a particular vessel. For instance, this is the case in which a prosthetic sequential aortal-femoral and femoral-distal bridge is to be realized such that an adapter according to Figure 2 can be inserted in corresponding position to the junction of the femoral vessel.

By referring to Figure 3, it can be observed that a third embodiment of the adapter according to this invention comprises two main conduits 1 and 1' both communicating with a branch conduit 2.

The embodiment of Figure 3 enables to utilize the adapter in performing arterial-venous vents, for instance in the case of dialyzed patients.

It is well known to those skilled in the art that a natural branching can be present in corresponding position to the connection of a vascular prosthesis. In such cases, the adapters illustrated in Figures 1, 2 and 3 could occlude the related connection mouth. To overcome such a drawback, a fourth embodiment of the adapter according to this invention, as shown in Figure 4, provides for the main conduit 1 to have apertures 4 in its external wall adapted to prevent any connection mouths to further blood vessels from being occluded. Also in this case, the perimetral edges of said apertures 4 can be tapered and /or realized with special partially bio-degradable and/or foamable shape recovering materials so as to minimize the step effect that can be generated in the lumen of the vessel.

The adapter of Figure 4 is related to the one of Figure 1; it should be understood that similar embodiments of the adapter could also

be realized in respect of the embodiments of Figures 2 and 3, without so departing from the scope of this invention.

Furthermore, an adapter having three apertures 4 in its lateral wall is shown in Figure 4. It should be understood, however, that the number of said apertures 4 in the lateral wall can also be different from three, without so departing from the scope of this invention.

A fifth embodiment of the adapter according to this invention (not shown in the Figures) provides for the external wall of the main conduit to have suitably shaped weakness lines that can be cut open by the surgeon during the intervent in order to remove some portions of the external wall, so as to connect the adapter to junction areas where natural branchings are present.

Further embodiments of the adapter according to this invention can also be provided with a metal core, such as a wire network, internally incorporated with the material of the adapter itself. In particular, such core is realized with inert bio-compatible materials, such as, for instance, steel and titanium and/or foamable shape recovering materials.

The utilization of the adapter for vascular anastomoses according to this invention makes the application of by-passes to vessels of small diameter possible.

Furthermore, the simplification realized in installing a vascular anastomosis by utilizing the adapter according to this invention makes it easier to apply methods of video-assisted surgery, that are less invasive than the presently utilized conventional surgery techniques.

This invention has been hereinbefore explained by way of illustration, but not by way of limitation, according to its preferred embodiment, but it should be understood that those skilled in the art can made variations and/or changes therein without departing from the scope of this invention, as defined in the attached claims.

CLAIMS

1.- An adapter for vascular anastomoses having perimetral edges, characterized in that it comprises at least one main conduit (1, 1') and at least one branch conduit (2), the prosthesis being realized with bio-compatible material.

2.- An adapter according to claim 1, characterized in that it comprises a single main conduit (1) and in that the axes of the main conduit (1) and of said at least one branch conduit (2) can include an acute angle (α) in the range of 15° to 75°.

3.- An adapter according to claim 2, characterized in that the axes of the main conduit (1) and of said at least one branch conduit (2) include an acute angle (α) in the range of 25° to 45°.

4.- An adapter according to claim 1, characterized in that it comprises two main conduits (1, 1') and a single branch conduit (2).

5.- An adapter according to any one of the preceding claims, characterized in that at least one branch conduit (2) comprises a second order branch conduit (3), the axes of said at least one branch conduit (2) and of said at least one second order branch conduit (3) including an acute angle (β) in the range of 15° to 75°.

6.- An adapter according to claim 5, characterized in that the axes of said at least one branch conduit (2) and of said at least one second order branch conduit (3) include an acute angle (β) in the range of 25° to 45°.

7.- An adapter according to any one of the preceding claims, characterized in that at least one of the conduits (1, 1', 2, 3) of the adapter has cylindrical or frusto-conical shape.

8.- An adapter according to any one of the preceding claims, characterized in that at least one of the conduits (1, 1', 2, 3) of the adapter has a circular cross-section.

9.- An adapter according to any one of the preceding claims, characterized in that at least one of the conduits (1, 1', 2, 3) of the adapter has one or more apertures (4) in its external wall.

10.- An adapter according to any one of the preceding claims, characterized in that at least one of the conduits (1, 1', 2, 3) of the adapter is provided with suitably shaped weakness lines in its external wall adapted to be cut so as to remove at least a portion of said external wall.

11.- An adapter according to any one of the preceding claims, characterized in that said bio-compatible material is Dacron® and/or GoreTex® and/or PTFE and/or polyurethane and/or Nitinol® and/or ePTFE.

12.- An adapter according to any one of the preceding claims, characterized in that said perimetral edges are tapered and/or realized with partially bio-degradable and/or shape recovering materials.

13.- An adapter according to any one of the preceding claims, characterized in that at least one of the conduits (1, 1', 2, 3) of the adapter is provided with an internal bio-compatible metal core.

14.- An adapter according to claim 13, characterized in that said internal metal bio-compatible core consists of steel and/or titanium and/or a shape recovering material.

15.- An adapter for vascular anastomosis according to any one of the preceding claims, substantially as illustrated and described.

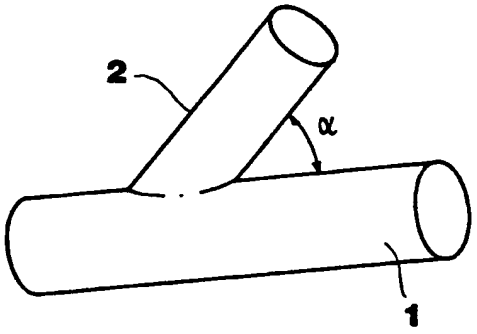


FIG. 1

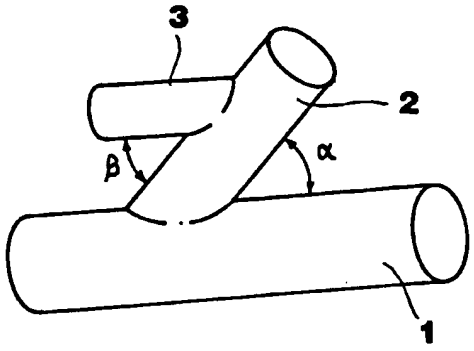


FIG. 2

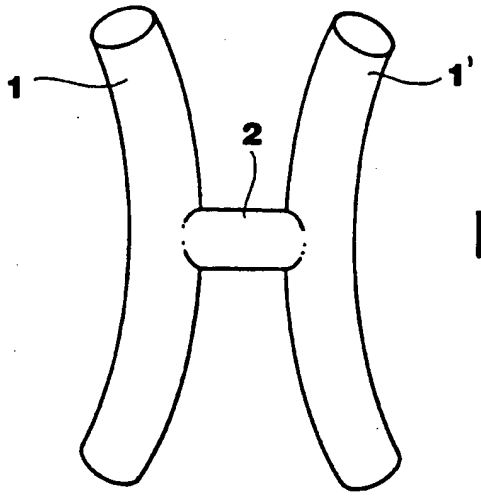


FIG. 3

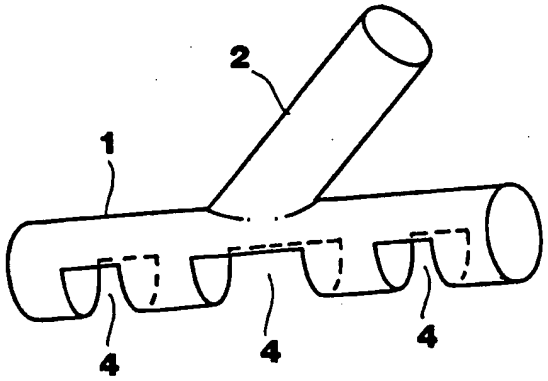


FIG. 4

INTERNATIONAL SEARCH REPORT

Interr ·nal Application No
PCT/IT 00/00058

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/11 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 686 252 A (FORNELL JACQUES ;BERTHOUMIEUX PHILIPPE (FR); BOUISSOU EMMANUEL (FR) 23 July 1993 (1993-07-23) page 1, line 28-32 page 2, column 7-11 page 2, line 15-21 figure 2 ---	1-8,12
X	WO 88 06865 A (BIEMANS ROGIER GUIDO MARIE) 22 September 1988 (1988-09-22)	1-8
Y	page 2, line 10-20 page 5, line 18-28 figure 5B ---	9,11
Y	DE 27 02 513 A (SUMITOMO ELECTRIC INDUSTRIES) 28 July 1977 (1977-07-28) page 4, paragraph 2 page 6, paragraph 3 ---	11
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 June 2000	16. 06. 00

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bichlmayer, K-P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Interr ·nal Application No
PCT/IT 00/00058

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 25 46 283 A (GAMBRO AG) 6 May 1976 (1976-05-06)	1,11,13
A	figure 2 page 4, paragraph 2 page 7, paragraph 1	10

Y	US 5 540 701 A (SHARKEY HUGH R ET AL) 30 July 1996 (1996-07-30) figure 3 column 5, line 35-41	9

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

ɜrnational application No.
PCT/IT 00/00058

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 15
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 6.2a PCT

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

.ormation on patent family members

Interr ''ional Application No
PC1/IT 00/00058

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
FR 2686252	A	23-07-1993	NONE		
WO 8806865	A	22-09-1988	NL	8700667 A	17-10-1988
			AU	1571588 A	10-10-1988
DE 2702513	A	28-07-1977	JP	1147667 C	26-05-1983
			JP	52089298 A	26-07-1977
			JP	57037338 B	09-08-1982
			AU	498725 B	22-03-1979
			AU	2111677 A	13-07-1978
			BE	850542 A	16-05-1977
			BR	7700349 A	20-09-1977
			CA	1081403 A	15-07-1980
			FR	2338691 A	19-08-1977
			GB	1577327 A	22-10-1980
			IT	1192217 B	31-03-1988
			NL	7700561 A,B,	25-07-1977
			SE	428524 B	11-07-1983
			SE	7700601 A	21-09-1977
			US	4208745 A	24-06-1980
DE 2546283	A	06-05-1976	SE	397769 B	21-11-1977
			CA	1066456 A	20-11-1979
			CH	604680 A	15-09-1978
			FR	2299013 A	27-08-1976
			GB	1511030 A	17-05-1978
			IT	1043580 B	29-02-1980
			JP	1286221 C	31-10-1985
			JP	51068992 A	15-06-1976
			JP	60005301 B	09-02-1985
			NL	7512868 A,C	06-05-1976
			SE	7413811 A	05-05-1976
			US	3993078 A	23-11-1976
US 5540701	A	30-07-1996	NONE		